



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Scientific Symposium on Advanced Therapy Medicinal Products 'Contribution, evolution, revolution'

10 October 2024

EMA, Amsterdam

Scientific Symposium on Advanced Therapy Medicinal Products (ATMPs) organised by the Committee for Advanced Therapies (CAT)

On 30 December 2008, the ATMP Regulation (Regulation (EC) No 1394/2007) came into operation and in January 2009, the CAT held its inaugural meeting.

Now, 15 years later, ATMPs have become an established part of the medicines' armamentarium: 27 gene- and cell/tissue-based medicines are offering treatment options for unmet medical needs.

This symposium will showcase how the work of the CAT has contributed to the regulatory framework for ATMPs in Europe and to the approval of these innovative products. It will also outline the evolution of CAT and its adaptation to the challenges posed by novel classes of ATMPs, always with the aim to ensure that high quality, safe and efficacious products become new treatment options.

The ATMP story does not end here: many more novel developments are at the horizon, each of them with the possibility to revolutionise patient care, with their own merits and challenges. The speakers and audience will discuss the vision for ATMPs for the next 15 years.

The audience will include members of the CAT, EMA committees and working parties, members of the regulatory authorities, representatives from industry and academia, patients- and doctors-representatives, policy makers and members from the public interested in ATMPs and the work of the CAT.

Agenda

Chaired by Ilona Reischl (CAT) and Patrick Celis (EMA)

Thursday 10 October 2024

9:00 Joining and technical checks

9:20 Welcome

Steffen Thirstrup, Chief Medical Officer and Ilona Reischl, CAT Chair **10'**

9:30 Session 1: Committee for Advanced Therapies (CAT): raison d'être

Chair: Caroline Pothet (EMA)

The ATMP Regulation and the Role of the CAT: have we delivered? **20'**
Ilona Reischl (CAT)

Patient involvement in the work of the CAT **20'**
Kieran Breen (CAT)

The contribution of CAT to the international development of ATMPs **20'**
Patrick Celis (EMA)

10:30 Session 2: How did the field of ATMPs evolve over time: the perspectives from the former CAT chairs

Chair: Ilona Reischl (CAT)

Presentation by **20'**
Christian Schneider (Pharmalex)

Presentation by **20'**
Paula Salmikangas (NDA)

Presentation by **20'**
Martina Schüssler Lenz (Paul-Ehrlich Institute, Germany)

11:30 Coffee break

12:00 Session 3: What is needed for the future?

Chair: Kieran Breen (CAT)

Fireside-chat session with the current and former CAT chairs 50'

Ilona Reischl (CAT), Christian Schneider (Pharmalex), Paula Salmikangas (NDA), Martina Schüssler-Lenz (PEI)

12:50 Lunch break

14:00 Session 4: What challenges will arise from ATMPs under development?

Chair: Andreea Barbu (BWP)

Presentations 90'

- The academia viewpoint: Luigi Naldini (San Raffaele Telethon Institute for Gene Therapy)
- The viewpoint from industry: Sibylle Herzer (Kite Gilead)
- The patients' perspective: Avril Daly (Retina International)

15:30 Coffee break

15:50 Panel discussion: ATMPs for the next 15 years

Chair: Patrick Celis (EMA)

Panel discussion with questions from the audience 65'

Speakers from previous sessions & Additional panellists from:

- Paschalia Koufokotsiou, European Commission, DG Santé
- Jacquelyn Awigena-Cook, Pharmaceutical industry organisations' representative
- Mencia de Lemus Belmonte, Patient organisations' representative from CAT
- Paolo Gasparini, Clinicians' representatives from CAT
- Andreea Barbu, BWP vice-chair
- Marcel Hoefnagel, Quality Innovation Group (QiG) chair

16:55 Closing remarks

Wrap up and closure of the meeting 5'

Ilona Reischl

End of the meeting: 17:00

List of speakers and panellists

Ilona Reischl	Austrian Medicines and Medical Devices Agency; CAT Chair
Kieran Breen	Parkinson's Europe; CAT Vice-chair
Patrick Celis	EMA, Office of Advanced therapies and Haematological Disease
Christian Schneider	Pharmalex
Paula Salmikangas	NDA
Martina Schüssler-Lenz	Paul-Ehrlich Institute, Germany
Luigi Naldini	San Raffaele Telethon Institute for Gene Therapy
Sibylle Herzer	Kite Gilead
Paschalia Koufokotsiou	European Commission, DG Santé D2
Jacquelyn Awigena-Cook	Bristol Myers Squibb
Mencia de Lemus Belmonte	Patient organisations' representative from CAT
Paolo Gasparini	Clinicians' representatives from CAT
Andreea Barbu	Medical Products Agency (Sweden); BWP Vice-chair of the BWP
Marcel Hoefnagel	Medicines Evaluation Board (Netherlands); QIG chair